



Phase II Annual Registration and Listing Pilot Instruction Guide

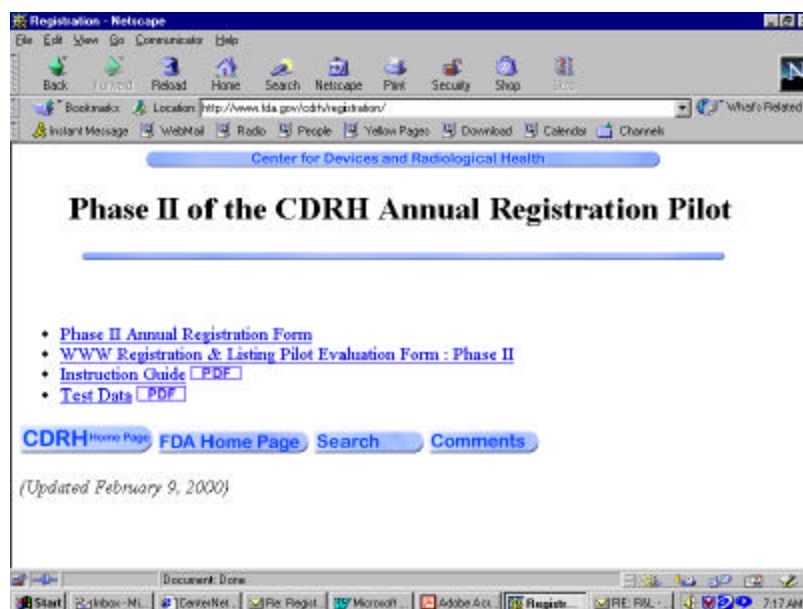
Center for Devices and Radiological Health
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Table of Contents

	Page
General Instructions	1
Login Entry Page	2
User profile Screen	4
Annual Registration Screen	5
Update and Submit Annual Registration	6
Passwords	9
Add or Delete an Establishment from Your Account	10
Acquire Ownership of Another Establishment	11
Transfer Ownership of an Establishment	12
Help	13
Evaluation Form	13
Exit the Application	13

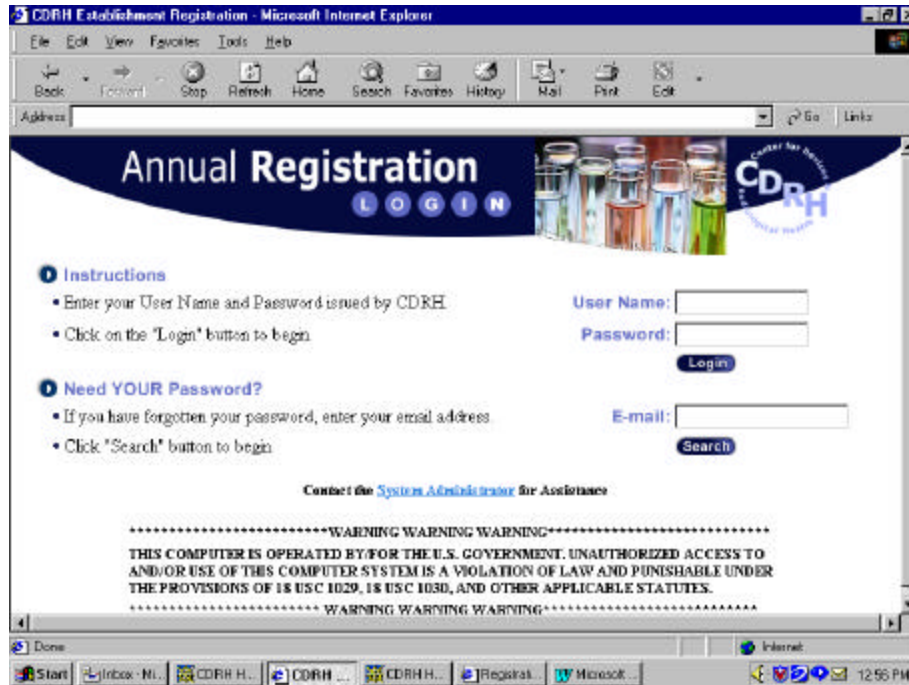
General Instructions

- Before starting this application check to see that your browser is set up to refresh a page each time you go to it.
- In IE go to Tools Menu; Internet Options; Settings (under Temporary Internet files). “Every Visit to the Page” should be selected.
- In Netscape go to Edit menu; Preferences; Advanced; Cache. “Every Time” under Document Cached should be selected.
- Another setting that you need to be aware of deals with encrypted files. In IE go to Tools Menu; Internet Options; select “Advanced”; under the heading of Security make sure that the item “Do not save encrypted pages to disk” is NOT selected
- Different browsers and even various versions of a browser may cause the screens in this application to appear slightly differently.
- Please remember – **No** actual records will be changed during this pilot. You will not be changing your company’s actual data that FDA maintains. If you find information about your company that you wished corrected, you will need to notify CDRH in writing.
- The information in the database will be “reset” after today’s training.
- **New!** An error trapping mechanism has been put in place for serious program errors. These are errors due to coding problems that prevent the Registration form from working properly. The error trap will automatically send emails to the programming team and to the system administrator with relevant information about the application error and the person who was logged in when the error occurred. The user will get a page that informs them that the error occurred and that CDRH has been notified. They can continue to use the application despite the error.
- **New!** You will receive email correspondence regarding updates that you have made in the system. Some email systems may handle these messages as an attached file. It may not be obvious that the attached file is an html file. If you receive a message from the system administration with an attached file, save the file and then open it with your browser.
- To get to Registration application enter the following URL:
<http://www.fda.gov/cdrh/registration>



- Select Phase II Annual Registration Form

Login Entry Page



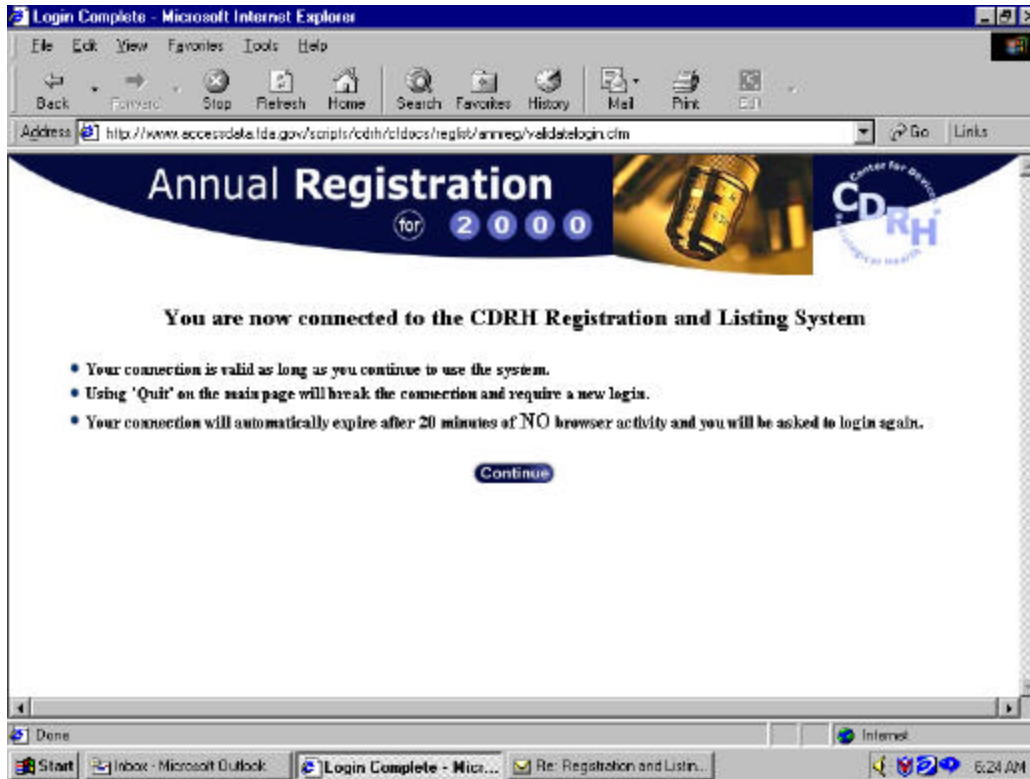
User Name and Password

- Enter your User Name and Password. In order to do this, start by placing your cursor in the User name field.
- Initially, each individual establishment will have a user name that is the same as its registration number.
- Select the “Login” button.
- Browser may display a window asking you if you want your computer to remember the password. For security reasons we recommend that you do **not** select yes to this option.
- Once you have entered the information correctly you will be taken to the next screen

Incorrect User Name or Password

- If you have incorrectly entered either the User name or Password, you will get a message indicating that they have not been entered correctly and to try again.
- You will be given 5 attempts to correct the information.
- After 5 attempts, you will get a screen telling you that no data can be entered into this account for 30 minutes.
- If you don't remember your password see page 9 for further instructions on how to obtain it.

Login Screen (Continued)



- Each time after login, you will see this screen
- If this is the first time you have logged into your account you will be taken to the Profile screen.
- If you have logged in previously you will be taken to the Registration page.

User Profile Screen

Annual Registration
Update Profile

Make changes to the information below and click on the 'Update' button. All fields are required.

User name (6 or more characters):

First Name:

Last Name:

Phone number:

E-mail address:

- This screen allows you to change your User Name and other basic information about you
- All fields are required on this screen.
- You may change the User Name as long as the new name is more than 6 characters.
- If you change the User Name, the system will expect that you login using that new User Name the next time you login.
- Enter the email address. This application will generate a variety of confirmation email messages that will be directed to the email address provided here.
- When done entering the information select “UPDATE”.
- A window will appear that will request you to enter the email address again. This is a process to ensure that your email address has been typed in correctly.
- If the second email address matches the first one you entered, a screen will appear stating that you profile has been updated. Select the “Continue” button to proceed.
- If the email addresses do **not** match, you will need to reenter the information. You can not proceed past this screen until the addresses match.

Annual Registration Screen



Options

- **Annual Registration**
 - Select the Establishment Number on the Left side of the screen to Update and Submit your annual registration.
- **Transfer of Ownership**
 - This will allow you to Acquire or Transfer establishments. See page 11 for further information.
- **User Options**
 - ◆ **Request New Password**
 - Allows you to request a new password. See page 9 for further information.
 - ◆ **Update Your User Profile**
 - See previous page for further information.
 - ◆ **Add/Remove another Establishment from your Account**
 - See page 10 for further information
- **Quit Application**
 - Select the Quit button in the upper left-hand corner of screen. See page 13 for further information

Update and Submit Annual Registration

General Information

- The alignment of the form may look slightly different on different browsers
- Buttons for OMB Statement and Legal Note are located at the top of the form
- General instructions on what to do with form are also listed
- Statement in Red indicates current status of establishment
- Can click on word Help or questions mark to get more detailed information. This will cause a separate window to appear
- You can tab through the items, use your mouse or use some combination of both
- Depending on your browser, some of the error and edit check messages may appear at different times

Part A

- Complete block A by checking only one box

Part B

- Enter information about the Registered Establishment. Indicate any changes or corrections to the information.
- All fields are required except for:
 - Establishment Division Name
 - Address 2
- Zipcode must correspond with state for addresses in the United States

Part C

- Establishment Types are listed in this part. Select all that apply.

Part D

- Owner/Operator information is entered in this part.
- If you check the box **“Same as Establishment Name and Address”** the information from Part B will be copied into this part. If you decide **prior** to transmitting this information that you prefer the original information, select the **“Reset”** button. This will restore the original information to Part D.
- All fields are required except for:
 - Business Division Name
 - Address 2
 - Phone extension
- Phone numbers may be entered with or without dashes
- Zipcode must correspond with state for addresses in the United States

Part E1

- If you have other Names for the registering establishment already entered into the system they will be listed in this part
- If a Name is no longer correct you can modify it or you can check the delete box to remove it

Part E2

- The purpose of this section is to record other names for the registering establishment that relate to device activities and that are different from the name entered in block B
- It is not required that you have other Business Trading names

Part F

- Official Correspondent information is entered in this part. FDA will direct important correspondence to the individual identified in this section
- If you check the box **“Same as Establishment Name and Address”** the information from Part B will be copied into this part. If you decide **prior** to transmitting this information that you prefer the original information, select the **“Reset”** button. This will restore the original information to Part F.
- All fields are required except for:
 - Business Division Name
 - Address 2
 - Phone extension
- Phone numbers may be entered with or without dashes
- Zipcode must correspond with state for addresses in the United States

Buttons at Bottom of Form

- Reset Button:
 - Prior to transmitting the data to FDA you can decide to reset the form to its original values by selecting the **“Reset Form”** button
- Cancel Button:
 - If you select the **“Cancel”** button all of the data you have entered will be lost and you will be returned to the Annual Registration Screen

Transmit data to CDRH Button

- To send the completed form to FDA select the **“Transmit Data to CDRH”** button.
- There are some edit checks that will take place on your data. If your data does not pass those edits you will get either:
 - a window explaining the problems with your data , OR
 - a screen listing the errors and explaining whether the information is missing or incorrect.
- No data will be sent UNTIL all of the errors have been resolved. Once all of the data has passed the error checks, the information must then go through a spell check process.

Spell Checker Messages

- FDA/CDRH is attempting to standardize the entry of firm names into the CDRH Registration and Listing system. In order to assist in this process, your data concerning Firm names will now be presented to you for review.
- Check that all words are spelled properly and that proper punctuation is used. Each Firm name will be shown and any changes that have been made to the name will be shown (Example: COMPANY abbreviated as CO.)
- The Main Guidelines for how names should be entered are listed on the right hand side of the screen.
- A complete list of abbreviations for common business terms can be found at:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/reglist/annreg/abbrevguidelines.cfm>
- It is mandatory that all forms of the words “Division” and “Subsidiary” be removed from the firm names. You will not be able to proceed any further in the process until that is done.
- Once that has been done you will be asked to review terms which were not found in the CDRH Registration & Listing dictionary. Use the checkbox on the right to indicate if the term is correct. Make corrections in the textbox provided.
- Once the data has passed through the spell checking process, the information will be sent to the FDA.

Confirmation Screen

- After your data has been transmitted to FDA you will see a Confirmation Page on your screen listing all of the data for that establishment
- In addition an email message confirming the data, will be sent to the email address listed in your user profile
- At this point in the process you can choose to return to the registration form that you have been working on or you can go back to the Annual registration Screen

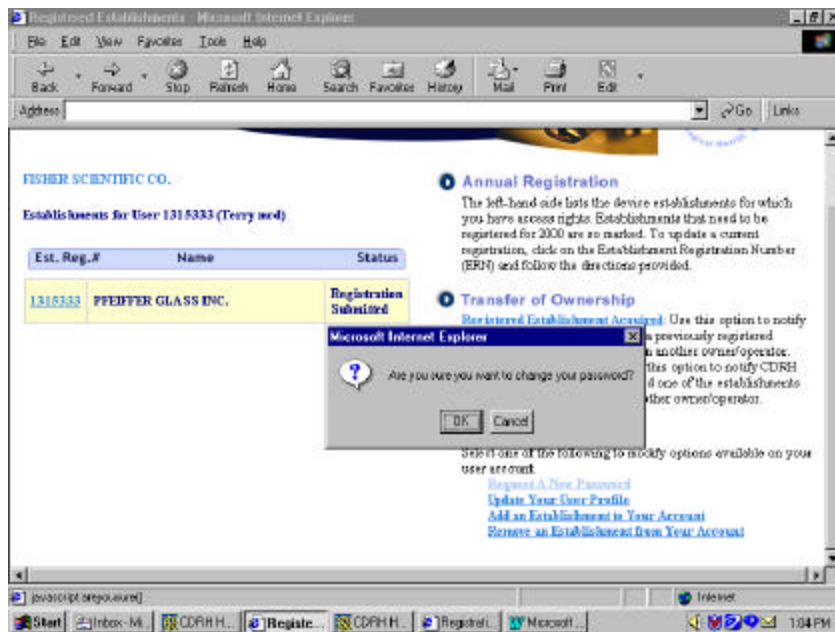
Passwords

Two options

- request a new password
- request that your current password be sent to you if you have forgotten it

New Password

- if you select “request a new password “ on the Annual Registration Screen, a box will appear asking you if you are sure you want to change your password



- If you select “OK” an email will be generated and sent to the email address in your user profile, which contains a new password. This is a machine generated password.
- There is no way that you can create your own password.

Forgot your password?

- If you have forgotten your password you may request that it be sent to you
- On the Login screen type the email address of the account that you wish the password for and select the “Search” button
- A list of all the Establishment Names and registration Numbers that have that email account in their profiles will appear
- Click on the User Name for the establishment that you wish the password for
- The password will be immediately sent to that email account

Add or Delete an Establishment from Your Account

Why would you want to do this

- You may be responsible for several establishments that you wish to consolidate under one account
- OR at some later point one or more of the establishments that you had consolidated under one account may become another person's responsibility.

To add an account

- Select an Establishment to add to your user account from the list below.
- Enter the password for the User Account that currently has control of the selected Establishment.
- Select the 'Add' button to transfer the Establishment to your User Account.

To delete an account

- Select one or more Establishments to transfer to another one of your user accounts
- Select your account from the drop down box to receive the establishments
- Select transfer to transfer the Establishments to the other user account

Acquire Ownership of Another Establishment

- Use this option to notify CDRH if your company has acquired a previously registered medical device establishment from another owner/operator.
- This is a multi-step process and before anything will be finalized, FDA must receive confirmation of this transfer from the company who currently owns it.
- Selecting this option will cause the following screen to appear

The screenshot shows a web browser window titled "Locate Previous Q/D [Establishment Acquired] - Microsoft Internet Explorer". The page has a header with the text "Transfer of Owner Operator (step-1)" and the CDRH logo. The main content area contains the following text and form fields:

If you know the 7 digit Establishment Registration Number assigned by CDRH, enter it here:

Otherwise, enter all or part of the Establishment Name here (3 character minimum):

State (optional):

Country (optional):

Buttons: Search, Reset, Cancel

- You can find the establishment that you are acquiring in several ways:
 - If you know the Registration number enter it
 - OR if you only know the Establishment name, you can enter all or part of the name
 - In addition you may enter the State or the Country
 - Once you have entered the data select the “Search” button
- You will see a receive a list of Establishments that match your selection criteria
- Select the establishment that you are acquiring
- OR if the establishment that you are acquiring is not on the list then select “Acquired Establishment is not on list below”. Fill in at least the required information (required fields are bolded) on the screen (more if you can) and hit the “continue” button
- Review the information listed. To transmit change in Owner/Operator information to FDA/CDRH click on the "Submit" button. The Previous Owner/Operator will receive an E-mail (if an address was supplied) notice requesting confirmation.

Transfer Ownership of An Establishment

- Use this option to notify CDRH if your company is selling a previously registered medical device establishment to another owner/operator.
- This is a multi-step process and before anything will be finalized, FDA must receive confirmation of this transfer from the company who is accepting it.
- Selecting this option will cause the following screen to appear:

- Find the establishment you are transferring by selecting it from the dropdown box
- You will then need to identify the firm that has purchased your establishment. This can be done in several ways:
 - If you know the Establishment number enter it
 - OR if you only know the name, you can enter all or part of the Establishment name
 - In addition you may enter the State or the Country
 - Once you have entered the data select the “Search” button
- You will see a receive a list of Establishments that match your selection criteria
- Select the firm that is purchasing your establishment
- OR if the establishment is not on the list then select “Establishment is not on list below”. Fill in at least the required information (required fields are bolded) on the screen (more if you can) and hit the “continue” button
- Review the information listed. To transmit change in Owner/Operator information to FDA/CDRH click on the "Submit" button. The New Owner/Operator will receive an E-mail (if an address was supplied) notice requesting confirmation.

Help

- As discussed in the section on the Registration form there is on-line assistance available to you while you are updating the form. Click on the word “Help” or on the Question mark in the yellow boxes
- In addition you can receive telephone assistance from CDRH by calling any of the following people for assistance:
 - Jim Motz 301-594-4550 x 156
 - Eileen Marshall 301-594-4550 x 157
 - Terry McDonald 301-594-4754 x 179
- Please use this help when you need immediate assistance in updating your information.
- Access to the System Administrator is also available by email at : jam@cdrh.fda.gov Use this account to immediately notify CDRH about such things as: you can not access your account or that you are unable to get the system to accept any changes to your records.
- Remember – **No** actual records will be changed during this pilot. You can not harm your company’s actual data that FDA maintains.

Evaluation Form

- The Evaluation form for the Registration Process is available at : <http://www.fda.gov/cdrh/registration/evalform.html>
- It is very important to us that you take the time to fill this form out. Even the most minor problem or suggestion will be reviewed and considered as we plan to move to the next phase of this pilot.
- Questions 1 through 10 are required.
- Please take the time to complete this form and submit all of your ideas regarding this process.

Exit the Registration and Listing Application

- Select the “Quit” button in the Left hand corner of the Registration Screen
- This will take you to a screen that tells you that Your FDA/CDRH Registration and Listing Session is now ended
- At this point hit your home button, go to one of your favorites or type in a URL to proceed to another site
- You also have the option on this screen to return to the Login Page